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cont'd  
a tissue engaging means including first and second opposed jaws for grasping,  
securing, and occluding body tissue and conduits;

a handle assembly;

an actuating means connecting the handle assembly and the tissue engaging  
means for actuating the tissue engaging means; and

a shaft member made of a malleable material and having a proximal end, a distal  
end and a longitudinal axis, the proximal end of the shaft member coupled to the handle  
assembly, the distal end of the shaft member coupled to the tissue engaging means, the  
actuating means extending axially through the shaft member, the shaft member  
configured to be kink resistant and to bend about some bending radius in response to a  
bending moment applied to the shaft member.

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## REMARKS

### I. Background

The present application was filed on 16 February 2001 with 52 claims as a continuation-in-part of issued U.S. Patent No. 6,139,563. In the first Office Action mailed on 6 August 2001, claims 1, 5, 6, 8 - 13, 16 - 24, 26 - 31, 33 - 38, and 40 - 43 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,945,920 to Clossick; claims 2 - 4, 7, 14, 15, 25, 32, 38, 39, and 44 were objected to as being dependent on a rejected base claim, but containing allowable subject matter; and claims 45 - 52 were indicated as allowable.

In response, Applicants amended claims 1, 13, 22, 29, 35 and 40 and claims 53 - 89 are added: amended claim 1 corresponded to allowable claim 2, newly added claim 53 corresponded to allowable claim 3, newly added claim 64 corresponded to allowable claim 7, amended claim 13 corresponded to allowable claim 14, amended claim 22 corresponded to allowable claim 25, amended claim 29 corresponded to allowable claim 32, amended claim 35 corresponded to allowable claim 38, newly added claim 75 corresponded to allowable claim 39, and amended claim 40 corresponded to allowable claim 44. Thus, in accordance with the Office Action of 6 August 2001, claims 1, 3 - 13, 15 - 24, 26 - 31, 33 - 37, 39 - 43, and 45 - 78 were in condition for allowance.

However, in the second Office Action mailed 20 March 2002, rather than the forthcoming notice of allowance the pending 89 claims were subjected to a restriction

requirement setting forth 19 “different species.”<sup>1</sup> In response, the Applicants elected claims 1 - 21.

In the Office Action mailed on 2 July 2002, claims 1 and 3 – 12 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,916,193 to *Stevens et al.*; and claims 13 and 15 - 21 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,643,303 to *Donahue*. In the Office Action mailed on 14 January 2003, claims 1 and 3 – 12 again were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,916,193 to *Stevens et al.*; and claims 13 and 15 - 21 again were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,643,303 to *Donahue*. The Office Action of 14 January 2003 was made final.

In this final rejection, the Office Action argued that “it is noted that the features upon which applicant relies (i.e. tissue engaging means and a handle assembly and an actuating means) are not recited in [claim 1 and its dependents].” In response to this final rejection, Applicants submitted an Amendment After Final on 6 March 2003 in which the tissue engaging means, handle assembly and actuating means are now recited in the body of claim 1 and its dependents. Nevertheless, on 1 April 2003 the Amendment After Final was refused.

After incurring the expense and delay of filing a continued examination request, the Office Action dated 23 June 2003 now withdraws the previous rejections and enters a new grounds for rejection. Specifically, claims 1, 3-13, and 15-21 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,474,057 to Makower et al. Claims 1 and 13 have been amended to eliminate the bending moment as the Office Action refuses to give any patentable weight. The claims as amended are set forth in the Appendix.

## **II. Discussion**

U.S. Patent No. 5,474,057 to Makower et al. (“*Makower*”) describes a laparoscopic dissection tension retractor device. A retractor and dissector (10) for internal surgical use on a patient's body has a tubular support (11) for passing into the patient's body. A proximal end (12)

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<sup>1</sup> In addition, in contrast to the MPEP the Office Action mailed 20 March 2002 restricted as against figures, not claims:

“In passing upon questions of double patenting and *restriction*, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence.”

Section 806 (Emphasis added).

on the tubular support is located outside the patient's body to provide access for the surgeon. A distal end (13) on the tubular support is located inside the patient's body to provide access within the patient for surgery. A control (19) is located at the proximal end of the tubular support. Articulated members (15) are movably positioned relative to the distal end of the tubular support so each of the articulated members allows swinging relative to the distal end. A rotator connects to the proximal end of the tubular support for movement relative to the control. An additional instrument moves independently of the tubular support when the articulated members and the distal tips cooperatively function on the tissue. The instrument passes simultaneously through a passage from the proximal end to beyond the distal end so the articulated members may position the tissue relative to the patient

The Office Action alleges that *Makower* teaches that the "first tube [is] configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending movement applied to the first tube." In support for this conclusory allegation, the Office Action cites Column 7, lines 4-16 of *Makower*. However, nothing in Column 7, lines 4-16 supports this allegation:

"The tubular support 11 can be made out of any material appropriate for the nature of its use and in particular a medical grade plastics, metals or ceramics may be used, however, the choice of material will undoubtedly be determined by the function of the particular configuration. While elongate tube 41 can be easily extruded U-shaped channels 40, machining in addition to extrusion, or molding may be needed to obtain the desired cross-sectional configuration necessary. It is expected that skilled artisans will be able to fashion a tubular support 11 from single or multiple pieces in a way which provides a thin wall and allows a maximum passage 16 therethrough while providing adequate strength for carrying the members 15 at the distal end 13 thereof."

Not only is there a complete absence of teaching of kink resistant and fatigue resistant and bending about some bending radius, but the inclusion of ceramics as an appropriate material actually teaches away from the claimed invention. The American Ceramics Society defines ceramics as typically crystalline in nature and formed between metallic and nonmetallic elements such as aluminum and oxygen (alumina- $\text{Al}_2\text{O}_3$ ), calcium and oxygen (calcia -  $\text{CaO}$ ), and silicon and nitrogen (silicon nitride- $\text{Si}_3\text{N}_4$ ). Thus, the American Ceramics Society lists the characteristics of ceramics as:

- hard,
- wear-resistant,

- brittle,
- refractory,
- thermal insulators,
- electrical insulators,
- nonmagnetic,
- oxidation resistant,
- prone to thermal shock, and
- chemically stable.

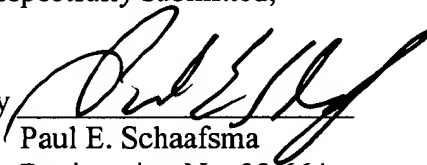
<http://www.ceramics.org>. Thus, *Makower* certainly does not disclose, suggest or teach use of a malleable material as the first tube configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the first tube. Therefore, claims 1, 3-13, and 15-21 recite patentable subject matter and are in condition for allowance.

### III. Conclusion

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

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## APPENDIX

1. (Five Times Amended) A surgical device comprising:

a tissue engaging means and a handle assembly;

an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means;

a shaft member comprising a first tube made of a malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the first tube adapted to be coupled to the handle assembly, the distal end of the first tube adapted to be coupled to the tissue engaging means, the actuating means adapted to extend axially through the first tube, the first tube configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the first tube[, the bending moment applied to the first tube ranging between about 6 in-lbs to 27 in-lbs].

13. (Three times Amended) A surgical device comprising:

a tissue engaging means including first and second opposed jaws for grasping, securing, and occluding body tissue and conduits;

a handle assembly;

an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means; and

a shaft member made of a malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the shaft member coupled to the handle assembly, the distal end of the shaft member coupled to the tissue engaging means, the actuating means extending axially through the shaft member, the shaft member configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the shaft member[, the bending moment applied to the shaft member ranging between 6 in-lbs to 27 in-lbs].